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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,725	09/08/2003	Louis C. Smith	AVSI-0010 P1 (108328.0015	8903

70578 7590 03/18/2009

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EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,725	SMITH ET AL.	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15,18,19 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15,18,19 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3-15, 18, 19, 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dev et al (US 6451002) in view of Simon (US 2002/0010415).

3. Dev discloses an electroporation device comprising a plurality of needle electrodes 32, a current waveform generator 115 for generating an electric pulse, a power source, a controller capable of managing the electroporation device to expose tissue adjacent to the needle electrodes to a substantially constant current (col. 4, lines 26-28). The device includes an input for inputting commands into the controller (col. 7, lines 40-44) and a display (col. 7, line 45). The needle electrodes form a circular array (see Fig. 2).

4. Dev discloses the method as claimed including the steps of programming an electrical pulse pattern into a controller, inserting a plurality of needle electrodes into the selected tissue, injecting a solution of macromolecules into the tissue by passing a syringe needle through the central channel (col. 4, lines 7-10, col. 8, lines 29-37), generating a pulse of electrical energy, and applying the pulse to the needle electrodes.

5. Claims 1, 27, 29 differ from Dev in calling for a waveform logger in communication with the controller. Simon teaches an electroporation device that includes a waveform logger that measures and records the voltage and current delivered through the electrodes so that the patient's response to the treatment can be compared to a baseline and monitored over time and the performance of the system and the pharmaceutical can be assessed (page 6, paragraph 0060).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Dev to include a waveform logger as taught by Simon so that the performance of the treatment can be assessed.

6. Claim 3 further differs from Dev in calling for an impedance tester. Simon teaches that the device comprises an impedance tester to ensure that the electrodes are in contact with the skin to prevent an output voltage increase that can damage the device (page 7, paragraph 0063). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Dev to include an impedance tester as taught by Simon to ensure that the electrodes are in contact with the skin to prevent a voltage increase that may damage the system. The device includes a handle 106 to which the electrode needles are fastened, and an activation switch 104 (col. 7, lines 50-57).

7. Claim 5 further differs from Dev in calling for the input device to include a keypad. Simon teaches that the device includes a user input in the form of a keypad for convenience and ease of use (page 7, paragraph 0067). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Dev to include a keypad as taught by Simon to increase convenience and ease of use.

8. Claims 9, 10 differ from Dev in view of Simon in calling for an optical serial port or an infrared port. However, wireless communication is well known in the medical device art in general and is provided in order to make use of the device easier for the patient and medical technician. At the time of invention, it would have been obvious to incorporate an optical serial port or an IR port into the invention to Dev in view of Simon. These devices are well known in the art and the motivation for the incorporation would have been known generally by one skilled

in the art to make use of the device easier for the patient and the medical technician and thereby enhancing the device in general.

9. Claims 11, 12 differ from Dev in calling for memory in communication with the controller. Simon teaches that the controller includes memory that allows the signals to be generated and controlled (page 14, paragraph 0139). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Dev to include a memory as taught by Simon so that the controller can generate the signal.

10. Claim 13 calls for the power source to be a battery. Dev and Simon are silent as to the source of power for the device. However, it is well known in the medical device art to use a battery to power an electrical device because it allows mobility of the patient and the device and eliminates cumbersome electrical cords. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Dev in view of Simon to include a battery as the power source as is well known in the medical arts to allow for the device to be used in any location.

11. Claim 19 calls for the circular array to be about 1.0 cm in diameter. Dev discloses that the circular array of needles may have a diameter suitably selected to provide the desired diameter to position around a tumor or other tissue to be treated (col. 4, lines 59-64). However, Dev fails to disclose the specific claimed diameter. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Dev in view of Simon to have a diameter of about 1.0 cm because Dev clearly contemplates that the device is capable of having any diameter so that the diameter can be suitable to meet the needs of the area to be treated.

12. Claim 27 further differs from Dev in calling the step of measuring the resistance. Simon teaches the step of measuring resistance to ensure that the electrodes are in contact with the skin to prevent an output voltage increase that can damage the device (page 7, paragraph 0063). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Dev to include the step of measuring resistance as taught by Simon to ensure that the electrodes are in contact with the skin to prevent a voltage increase that may damage the system. The device includes a handle 106 to which the electrode needles are fastened, and an activation switch 104 (col. 7, lines 50-57).

13. Claim 28 differs from Dev in calling for the step of recording data using a waveform logger in communication with the controller. Simon teaches an electroporation device that includes a waveform logger that measures and records the voltage and current delivered through the electrodes so that the patient's response to the treatment can be compared to a baseline and monitored over time and the performance of the system and the pharmaceutical can be assessed (page 6, paragraph 0060). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Dev to include recording data using a waveform logger as taught by Simon so that the performance of the treatment can be assessed.

Response to Arguments

14. Applicant's arguments filed 12/11/08 have been fully considered but they are not persuasive.

15. Applicant argues that Dev fails to teach a controller which is capable of managing the electroporation device to expose tissue to a constant current. The examiner disagrees and points applicant to Col. 7, lines 62-65 of the Dev disclosure wherein it is disclosed that the system

delivers pulses that rise to a set voltage and stay at that voltage for a period of time. This is interpreted to be a constant current delivered by a controller. Even though Dev fails to explicitly use the term controller, it is clear that there is a component controlling the delivery of the current to the device.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
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